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| 29053 7590 04/07/2009 FULBRIGHT & JAWORSKI L.L.P 2200 ROSS AVENUE | | | EXAMINER | |
| | | | MEHTA, PARIKHA SOLANKI | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Application No. Applicant(s) 10/766,707 FLOYD ET AL. Office Action Summary Examiner Art Unit PARIKHA S. MEHTA 3737 -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS. WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status 1) Responsive to communication(s) filed on 30 January 2009. 2a) This action is FINAL. 2b) This action is non-final. 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. Disposition of Claims 4) Claim(s) 1-12 and 14-38 is/are pending in the application. 4a) Of the above claim(s) _____ is/are withdrawn from consideration. 5) Claim(s) 9-12.14-23 and 35-38 is/are allowed. 6) Claim(s) 1-8 and 24-34 is/are rejected. 7) Claim(s) _____ is/are objected to. 8) Claim(s) _____ are subject to restriction and/or election requirement. Application Papers 9) The specification is objected to by the Examiner. 10) ☐ The drawing(s) filed on is/are: a) ☐ accepted or b) ☐ objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. Priority under 35 U.S.C. § 119 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. Attachment(s)

1) Notice of References Cited (PTO-892)

Notice of Draftsperson's Patent Drawing Review (PTO-948)

Information Disclosure Statement(s) (PTO/SB/08)
 Paper No(s)/Mail Date ______.

Interview Summary (PTO-413)
 Paper No(s)/Mail Date.

6) Other:

5) Notice of Informal Patent Application

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DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis
for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- Claims 24-27 are rejected under 35 U.S.C. 102(b) as being anticipated by Pruter (US Patent No. 6,296,614), hereinafter Pruter ('614), of record.

Pruter ('614) discloses a needle guide comprising a releasable latch 6 configured to mate with a proximate end of an ultrasonic probe 4, a channel 38 configured to accept the longitudinal axis of an elongated needle 12, wherein the channel lies along the longitudinal axis of the ultrasound probe when the guide is mated with the latch, the channel defining a pre-established closing angle with respect to a location below the surface of an object, and a slide configured to traverse the channel, the slide applying controlled clamping force on the needle (col. 2 lines 33-50).

Claim Rejections - 35 USC § 103

- 3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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 Claims 1-8 and 28-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pruter (US Patent No. 6,296,614), hereinafter Pruter ('614), of record, in view of Hayakawa (US Patent No. 5, 967, 985), hereinafter Hayakawa ('985).

Pruter ('614) teaches a method and apparatus for guiding a needle while attached to an ultrasound transducer probe, wherein the guide includes a latch, a longitudinal and cross-sectionally round channel/guide 40 configured to accept a needle, and a latch 92 that is capable of sliding over the needle and applying controlled clamping force on the needle (Figs. 2 & 4). The system of Pruter ('614) includes a bracket 6 that attaches to the probe (Fig. 2, col. 2 lines 37-39), wherein the bracket is adapted to accept, one at a time, a plurality of needle guides of varying gauge (col. 9 lines 1-5). Pruter ('614) further includes slots for fitting over a transducer (Fig. 2), a flexible tab 36, a tapered wedge 38 and a pivot point at its proximal endPruter ('614) additionally teaches the latch to include a funnel shaped body 40 and an overhang portion on the latch 92 (Fig. 4) that prevents the needle from becoming disengaged from the guide without first moving the latch to an open position, wherein the overhang constitutes pivoting means for controlling the release of the needle as claimed. Pruter ('614) sets forth steps for advancing a biopsy needle through the guide while the guide is attached to the transducer, and for separating the transducer assembly from the needle after insertion (col. 5 lines 19-34). Pruter (*614) teaches that the clamping mechanism is specifically adapted for the particular size of the medical device (col. 5 lines 1-9), i.e. that it is keyed to the dimension/gauge of the needle. The enclosed needle guide channel of Pruter ('614) constitutes the claimed slide which applies a degree of clamping force on the needle, wherein "slide" is interpreted to mean "a guiding surface along which something slides" as set forth by Merriam Webster.

Pruter ('614) does not teach the inclusion of multiple device supports having different attack angles. In the same field of endeavor, Hayakawa ('985) teaches that it is helpful to have multiple guides of differing attack angle in order to more accurately position a needle with respect to the depth of the target within the patient (col. 5 lines32-48, col. 27 line 65 – col. 28 line 3). It would have been obvious to one of ordinary skill in the art to have modified Pruter ('614) to duplicate and modify the needles guide of Pruter ('614) to yield multiple guides, each guide having a different angle of attack, in view of the teachings of Hayakawa ('985).

Allowable Subject Matter

Claims 9-12, 14-23 and 35-38 are allowed.

Regarding claims 9-12, 14 and 15, the prior art of record does not fairly teach or suggest a medical device guide including a latch comprising a tapered wedge portion configured to be positioned below a seated rod.

Regarding claims 16-23, the prior art of record does not fairly teach or suggest a method of releasably attaching a medical device to a probe, including a step of controlling clamping of the medical device to the probe with a slidably coupled latch comprising an upper surface and lower surface, the lower surface including a wedge portion which tapers upward.

Regarding claims 35-38, the prior art of record does not fairly teach or suggest a method of releasably attaching a needle to an imaging probe, wherein the method includes the step of releasably attaching a needle to the needle guide by sliding a clamping mechanism within one of a plurality of needle guides.

Response to Amendments and Arguments

- 2.. Applicant's amendments are sufficient to overcome the previous claim objections, objection to the specification and rejections under 35 U.S.C. 112, which are hereby vacated accordingly.
- 3. Applicant's arguments regarding claims 9-12, 14-23 and 35-38 are persuasive; those claims are allowed herein.
- 4. Applicant's arguments regarding claims 1-8 and 24-34 have been fully considered but are not persuasive.

Regarding claims 1-8, Applicant contends that the claimed bracket is distinguishable over the prior art because the prior art purportedly requires that the entire bracket be changed in order to change the angle of attack, whereas the present bracket does not need to be removed to change the angle. Examiner maintains that claims 1-8 do not positively recite this limitation; accordingly, the references meet the claim.

Regarding claims 24-27, Applicant argues that, if an element permits sliding, it cannot also be applying a controlled clamping force. Examiner maintains that an element can in fact permit limited movement (i.e. sliding) by applying a clamping force that is strong enough to hold the needle in the channel without completely restricting its movement.

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Regarding claims 28-34, Applicant argues that neither Pruter ('614) nor Hayakawa ('985) teach the step of releasably connecting the needle guide to the bracket; Applicant contends that the prior art requires removal of both the needle guide and bracket in order to change needle guides. Examiner respectfully directs Applicants' attention to Figures 4 and 5 of Pruter ('614), as well as col. 3 lines 18-30, wherein the reference teaches releasable attachment of the needle guide to the bracket. These teachings, combined with those of Hayakawa ('985) to provide needle guides of multiple angles, do in fact meet the claims.

As Applicant's arguments regarding claims 1-8 and 24-34 are wholly unpersuasive for at least the foregoing reasons, the previous rejection of those claims in view of the prior art is maintained and reiterated herein.

Conclusion

 THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to PARIKHA S. MEHTA whose telephone number is (571)272-3248. The examiner can normally be reached on M-F, 8 - 4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 571.272.4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/BRIAN CASLER/ Supervisory Patent Examiner, Art Unit 3737

/Parikha S Mehta/ Examiner, Art Unit 3737